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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,503	03/10/2000	Michael A. Masini	MED-02702/29	4920

7590                    09/19/2002

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[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

3732

DATE MAILED: 09/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/523,503	MASINI, MICHAEL A. <i>(Signature)</i>
	<b>Examiner</b>	<b>Art Unit</b>
	Eduardo C. Robert	3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 September 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 8-16 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 03 September 2002 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on 03 September 2002 is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on September 3, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/523,503 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Drawings***

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on September 3, 2002 have been approved.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 12-15 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 12, lines 3-4, applicant positively recites part of a human, i.e. "a movable member which references one of a non-prominent condyle and trochlear regions". Thus claims 12-15 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

*Specification*

The specification is objected to as failing to provide clear support for the claim terminology. 37 CFR § 1.75(d)(1) requires that terms and phrases used in the claims find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description. Specifically, the terms “movable member”, “movable guide”, “reference guide” do not appear in the specification.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12 there exists an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear. In the preamble, line 1, applicant recites “Apparatus” with the non-prominent condyles separated by a trochlear region being functionally recited, i.e. “for resecting a distal femur having prominent and non-prominent condyles separated by a trochlear region...”, thus indicating that the claim is directed to the subcombination, “Apparatus”. However, in lines 3-4, applicant positively recites the non-prominent condyles and trochlear region of the distal femur as part of the invention, i.e. “a fixture including a movable member which references one of a non-prominent condyle or trochlear region...”, thus indicating that the combination, apparatus and non-prominent condyle

or trochlear region, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Since claiming the combination of the apparatus and the non-prominent condyle or trochlear region makes such claim(s) directed to non-statutory subject matter, applicant should amend the claims so as to **remove all positive recitations** of the non-prominent condyle or trochlear regions. As such, the claim(s) would be directed to the subcombination, Apparatus, and will be considered as such for examination purposes.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-13, 15, and 16, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Whiteside.

Whiteside discloses an apparatus comprising a fixture (see Figure 8) including a movable member 81, and a cutting guide 80. The apparatus further comprises a intramedullary rod 30 and a reference guide 82. The movable member 81 and reference guide 82 are movable along the rod 30. The apparatus also comprises a prosthesis (see Figure 23). Whiteside further discloses a method including the steps of installing the fixture onto a distal femur which references, i.e. refers to or indicate, the non-prominent condyle or trochlear region (see Figure 20) and resecting the femur in accordance with a reference or indication made by the fixture. Other steps include placing the intramedullary rod in the distal femur, moving a guide, i.e. part of

the fixture, until the guide touches the non-prominent condyle or trochlear region (see Figure 20).

Claims 8-13 and 16, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by White.

White discloses an apparatus comprising a fixture (see Figure 1) including a movable member, and a cutting guide 113. The apparatus further comprises a intramedullary rod 37 and a reference guide 91. White further discloses a method including the steps of installing the fixture onto a distal femur which references, i.e. refers to or indicate, the non-prominent condyle or trochlear region (see Figures 9-19) and resecting the femur in accordance with a reference or indication made by the fixture. Other steps include placing the intramedullary rod in the distal femur, moving a guide, i.e. part of the fixture, until the guide touches the non-prominent condyle or trochlear region.

Applicant is reminded that an anticipation under 35 U.S.C. 102(b) or 102(e) is established when a single prior art reference discloses, **either expressly or under principles of inherency**, each and every element of a claimed invention. *RCA Corp. v. Applied Digital Data System, Inc.*, 730 F.2d 1440, 221 USPQ 385 (Fed. Cir. 1984). Furthermore, it is well settled that **the law of anticipation does not required that the reference teach what appellant is teaching or has disclosed, but only that the claims on appeal “read on” something disclosed in the reference**, i.e. all limitation of the claims are found in the reference. *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1083). Moreover, **it is not necessary for the applied reference to expressly disclose or describe a particular element or limitation of a rejected claim word for word as in the rejected claim so long as the reference inherently**

**discloses that element or limitation.** *Standard Havens Products Inc. v. Gencor Industries Inc.*, 953 F.2d 1360, 21 USPQ 2d. 1321 (Fed. Cir. 1991).

***Response to Arguments***

Applicant's arguments filed on January 14, 2002 have been fully considered but they are not persuasive.

In response to applicant's argument that Whiteside is entirely silent with regard to referencing any feature of the distal femur, it is noted that Whiteside clearly refers, i.e. indicates, the non-prominent condyle or trochlear region (see Figure 20).

In response to applicant's argument that Whiteside does not have a movable member which references one of non-prominent condyles or trochlear regions, it is noted that this recitation in claim 12 is considered non-statutory subject matter since applicant positively recites part of a human, i.e. a non-prominent condyle and trochlear regions, which is non-statutory. A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970). It is noted that this can be solved by reciting "a non-prominent condyle and trochlear regions" functionally, e.g. for referencing one of a non-prominent condyle and trochlear regions".

In response to applicant's argument that claim 12 includes a limitation that the cutting guide is used to resect a femur in accordance with the reference made, it is noted that the manner in which a device is intended to be employed does not differentiate the claimed apparatus from

prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

In response to Applicant's argument that White does not include certain features of Applicant's invention, the limitations on which the Applicant relies (i.e., measuring the distal end of either condyle or the trochlear region) are not stated in the claims. Therefore, it is irrelevant whether the reference includes those features or not.

*Allowable Subject Matter*

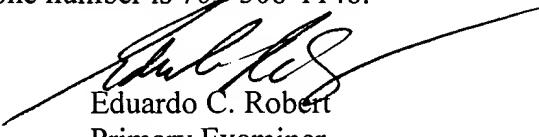
Claim 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Eduardo C. Robert  
Primary Examiner  
Art Unit 3732

E.C. Robert  
September 18, 2002